DING HWA CO., LTD.
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DEC 30 2013

510(k) SUMMARY (According to 21 CFR 807.92)

510(k) Owner's Name	DING HWA CO., LTD. #121, Section 3, Zhongshan Road, Dacun, Chang-Hua, Taiwan, R.O.C. 51542 Phone: +886 4 852 5755 Fax: +886 4 852 5795 Email: info@cliqmedical.com Website: www.cliqmedical.com
Name of Contact	Robert O. Dean Compliance Systems International, LLc. 1083 Delaware Ave. Buffalo, NY 14209 Phone: +01.716.440.7362 Email: compliancesystems@yahoo.com
Date Of Submission:	July 28,2013
Trade Name	**Cliq Aspirator, DV-300**
Common Name	Aspirator
Classification Name	Powered suction pump (21 CFR 878.4780, Product Code JCX, classification: class II)
Panel	General & Plastic Surgery
Intended Use	The device is to be used to remove fluids from the treated tracheotomy patient airway.
Device Description	The predicate devices and the subject device have the same technological characteristics. Those devices are intended to be used to remove fluids from the treated tracheotomy patient airway. It creates a negative pressure (vacuum) that draws the fluids through disposable tubing that is connected to a collection jar. The fluids are trapped in the collection jar for the proper disposal. The devices are for use on the order of a physician only. If practiced out of the hospital, the care giver has to be trained and recorded. The predicate devices and the subject device are the portable AC powered suction pumps. Each one consists of an on/off switch, a pump unit, a non-detachable flexible power cord, collection jar, relief valve, pressure gauge, pressure adjustment knob, bacteria filter, suction tubing. The major differences between the predicate devices and the subject device are the capacities and dimensions.

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SubjectDeviceComparedtoLegallyMarketedPredicateDevices

Comparison items	Predicate device 1	Predicate device 2	Subject device
Proprietary name	SPARMAX Aspirator TC-2000V	SPARMAX Aspirator VC-701	Cliq Aspirator DV-300
Manufacturer	Ding Hwa Co., Ltd.	Ding Hwa Co., Ltd.	Ding Hwa Co., Ltd.
5109k0 number	K080005	K080005	TBA
Regulatory number	878.4780	878.4780	878.4780
Product code	JCX	JCX	JCX
Classification	II	II	II
Common name	Aspirator	Aspirator	Aspirator
Classification identification	Powered suction pump	Powered suction pump	Powered suction pump
Indications for Use	The device is to be used to remove fluids from the treated tracheotomy patient airway.	The device is to be used to remove fluids from the treated tracheotomy patient airway.	Same
Collection tubing Length / material	180cm / PVC	180cm/ PVC	Same
Connection tubing length / material	400mm / Silicon	400mm / Silicon	Same
Internal battery	None	None	Same
Adaptor	None	None	Same
Bacteria filter	Appointed	Appointed	Same
Thermal switch	Appointed	Appointed	Same
Operating temp.	0 ~ 40°C	0 ~ 40°C	Same
Operating relative humidity	0~95%	0~95%	Same
Storage & transport temp	-40°C ~ 70°C	-40°C ~ 70°C	Same

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Storage & transport humidity	0 ~95%	0 ~95%	Same
Where used	Hospital	Hospital	Same
Standards complied	IEC 60601-1-2, UL 60601	IEC 60601-1-2, UL 60601	IEC 60601-1-2:2007
	CAN/CSA-C22.2 No.68~92	CAN/CSA-C22.2 No.68~92	IEC 60601-1:2005 +C1:2006+C2:2007
	UL 1450	UL 1450	ISO 10079-1:2009
			IEC 60601-1-11:2010
Sound level	< 54dB	< 54dB	< 50dB
Vacuum(Max.)	650mmHg	650mmHg	620mmHg
Air flow rate	>32 LPM	>16 LPM	>18 LPM
Electrical requirements	110-120 VAC, 60Hz, 1.2A(max)	110-120 VAC, 60Hz,0.9A(max)	110-120 VAC, 60Hz,0.5A(max)
Size (L*W*H) (mm)	380*165*240	340*155*210	300*165*190
Weight	5.2kg	4.25kg	3.5 kg
Collection jar	1800c.c.	800c.c.	800c.c.

Summary of Comparison:

In terms of similar comparison items, i.e., intended use / place, construction, accessories, function, safety, operating / storage environmental conditions, compliance with the same Electromagnetic Compatibility Standard, IEC 60601-1-2:2007, the Cliq aspirator DV-300 does not raise any safety and effectiveness aspects, so it is substantially equivalent to the predicate devices used for this application.

Also the predicate devices comply with CAN/CSA-C22.2 No.68~92 and the subject device complies with IEC 60601-1:2005, both standards concern about the general requirements for safety of the medical electrical equipment. Further, the predicate devices comply with the UL 1450 and the subject device complies with ISO 10079-1, both standards are related with the safety requirements for the medical electrically powered suction equipment. At last, for the purpose of the safety of the electrical equipments used in the homecare environment, the subject device complies with the standard, IEC 60601-1-11:2010. This offers more safety and effectiveness to the subject device than the predicate device.

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The major difference between the subject device and the predicate devices is the electrical power. The subject device has a less electrical power than the predicate devices. This leads to the differences of the sound levels, maximum vacuum levels, air flow rates, sizes, weights, and the collection jars. The differences are not related to the safety and effectiveness,

In conclusion, the subject device does not raise any safety and effectiveness compared to the predicate devices, thus the subject device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 30, 2013

Ding Hwa Corporation, Ltd
% Mr. Robert O. Dean
Compliance Systems
1083 Delaware Avenue
Buffalo, New York 14209

Re: K132308
Trade/Device Name: Cliq Aspirator, DV-300
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: JCX
Dated: November 7, 2013
Received: November 14, 2013

Dear Mr. Dean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
2013.12.30 16:24:13 -05'00'

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number: K132308

Device Name: Cliq Aspirator, DV-300

Indications for Use :

The device is to be used to remove fluids from the treated tracheotomy patient airway.

Prescription Use √ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DSD—DIVISION SIGN-OFF
Division of Surgical Devices
510(k) Number: K132308

Long H. Chen -A

for BSA